

## REMARKS

Claims 1, 36, 39 and 57 are currently pending. Claim 56 has been cancelled herein. No new matter has been added.

### ***Rejections under 35 U.S.C. § 101***

Claims 1, 36, 39 and 57 were rejected under 35 U.S.C. §101 as the examiner contends that the claimed invention is not supported by substantial asserted utility or a well established utility. The examiner states that the Gerlach Declaration under 37 C.F.R. 1.132 which provides evidence that the nucleic acid encoding the instantly claimed polypeptide is over-expressed in certain cancer cells, does not disclose if the protein is over-expressed. The examiner has invited the applicant to present evidence that protein over-expression correlates with cancer or other diseases to obviate this rejection. Applicant provides herewith, a Declaration under 37 C.F.R. §1.132 by Dr. Michael Jeffers presenting such evidence. Specifically the Jeffers Declaration, follows the teachings of the specification in order to detect the presence or absence of NOV1b protein in a biological sample by contacting the sample with a compound or agent capable of detecting NOV1b protein (see specification page 142, lines 27-31). Such an agent for detecting Nov 1b protein is an antibody according to the specification (see page 118, line 13 to page 121, line 33 and at page 143, lines 4-19). The Jeffers Declaration shows that certain cancers shown to over-express nucleic acid encoding the presently claimed polypeptide, SEQ ID NO:4 (as presented in the Gerlach Declaration) also express the polypeptide, SEQ ID NO:4 as detected by FACS analysis with antisera specifically binding to SEQ ID NO:4. In addition, the Jeffers Declaration shows that a cancer that does not over-express the nucleic acid encoding polypeptide SEQ ID NO:4, does not express the polypeptide SEQ ID NO:4 by the same FACS analysis. Therefore the polypeptide SEQ ID NO:4 is useful for differentiating cancers, such as breast and ovarian cancer from normal tissues. Applicants thereby respectfully request that the rejection be withdrawn.

### ***Rejections under 35 U.S.C. § 112***

Claims 1, 36, 39 and 57 are similarly rejected under 35 U.S.C. §112 as the examiner states that since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. Applicant submits that there is a credible, specific and substantial

asserted utility for claimed polypeptide SEQ ID NO:4 and that in view of the Jeffers Declaration and remarks above that this rejection has been overcome and should be withdrawn.

### CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Wendy L. Davis', with a large, stylized loop at the end.

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